



The Pregnancy Study: Participant Information Sheet

You are invited to take part in the Gomeri Gaaynggal Study. This study is being run by Associate Professor Kirsty Pringle from the University of Newcastle in partnership with the Gomeri Gaaynggal Advisory Committee, the Tamworth Aboriginal Medical Service (TAMS), and the Tamworth Local Aboriginal Land Council (TLALC).

Before you decide if you want to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with your family.

1. Why is this research being done?

We know that many chronic diseases like kidney disease and diabetes begin in the womb when mum is pregnant. This study aims to better understand what can provide a long and healthy life for Aboriginal Australian mothers and their babies.

We are working with the community to gather data and using this data to develop community-based programs to provide a healthy start to life for all Aboriginal Australian children. We will also record things about your health while pregnant. This is so that we can find out what could improve pregnancy outcomes and long-term health.



2. Who can be involved?

- Aboriginal Australian women who are currently pregnant.
- Non-Aboriginal women who are currently pregnant with an Aboriginal baby.

3. Are there any reasons why this study may not be suitable for me?

If you are not planning to stay in the Tamworth area for your whole pregnancy and/or don't plan on going to the Tamworth Aboriginal Medical Services (TAMS) for your pregnancy care, this study may not be right for you. Ideally, we would like families to be planning to stay in the area so we can contact you to see how you and your baby are going throughout your pregnancy. If you are less than 16 years old, are highly dependent on medical care, have a mental impairment or intellectual disability or poor understanding of English this may not be suitable for you.

4. What happens if I join the pregnancy study?

If you agree to participate in this study, you will be asked to sign the Participant Consent Form. One of our Aboriginal staff will be able to help you and answer any of your questions or concerns. You do not have to take part in all parts of the study and our consent forms are set up so that you can tick only the parts of the study you want to take part in.

If you chose to take part in the pregnancy study, we will try and organise three visits during your pregnancy. These will be spaced out so we will try and see you once at the beginning of your pregnancy, once in the middle and once towards the end of your pregnancy.

Surveys: We will ask you about a few questions so that we can better understand what things effect your health and the health of your baby during pregnancy. These include:

- The things you eat during pregnancy
- Your mental health
- Stressful life events and how these affect you
- Your experiences of discrimination (if any)
- Smoking
- Your general health and health history, and
- Demographics (things like income, employment, and education).



These surveys can be done in person with our Aboriginal staff when you attend the Tamworth Aboriginal Medical Services for your study appointment. They can also be done online at home if you prefer.

Body measurements: Using a special scale (called an InBody machine), we will measure what your body is made up of (water, muscle, fat) three times throughout your pregnancy. We will also measure your blood pressure, weight, height and the size of your waist, arms, and legs three times throughout your pregnancy.

Biological samples: Biological samples (like blood, urine, and spit) can tell us a lot about your health. We will ask to take blood, urine, and spit samples from you on three occasions during your pregnancy. Some of these samples may be additional to those collected as part of your normal pregnancy care. If you do not want to provide a sample for any reason you can still be part of the study.

See the list below for each sample and a short description of why we would like to collect it:

- Blood: We ask your permission to collect blood samples (about 2 tablespoons or 30mL) on three occasions during your pregnancy. The blood will be tested for hormones and markers of kidney and heart health, stress, infection, nutrition, markers of inflammation and chronic disease.
- Urine: We ask your permission to collect urine samples (about half a cup or 50mL) on three occasions during your pregnancy. The urine will be tested for hormones and markers of kidney and heart health, stress, infection, nutrition, markers of inflammation and chronic disease.
- Saliva (spit): We ask your permission to collect spit samples (about 2 teaspoons or 10mL) on three occasions during your pregnancy. The saliva will be tested for markers of stress and cigarette exposure.

Ultrasound: As part of routine low-risk care women usually get two ultrasounds around 12 weeks and 28 weeks of pregnancy. If you are referred to Dr Jyoti Chaku at any time during your pregnancy than we will also take some extra measurements to look at your baby's kidneys.

Medical records: Researchers need to find out about your medical health, pregnancy, and past pregnancies. We will also need some information about your baby, such as ultrasound information and your babies age and weight at birth. We will get this information from your medical records with your permission.

5. Study Timeline:

Study Visit	Surveys to complete	Body measurements taken	Biological samples taken	Time taken	Where
Visit 1 (Weeks 1-13 of pregnancy)	8*	InBody, blood pressure, height, weight and the size of your waist, arms, and legs	Blood, urine, saliva (spit)	3 hours and 15 minutes*	TAMS
Visit 2 (Weeks 14-26 of pregnancy)	6*	InBody, blood pressure, height, weight and the size of your waist, arms, and legs	Blood, urine, saliva (spit)	3 hours and 15 minutes*	TAMS
Visit 3 (Weeks 27-40 of pregnancy)	7*	InBody, blood pressure, height, weight and the size of your waist, arms, and legs	Blood, urine, saliva (spit)	3 hours and 15 minutes*	TAMS

* If you grant the study permission to access your medical records the number of surveys you may be asked to complete may be reduced. This is because we can get some of this information from your medical records. This should decrease the amount of time each visit takes. You will also be given the chance to do some of these surveys online at home before or after your study appointment.

6. What will happen to my samples?

Your samples will be tested and stored at the Hunter Medical Research Institute in Newcastle. Your samples will only be kept for a maximum of 5 years after the study end date.

7. What if I don't want to take part in this study, or if I want to withdraw later?

Participation in the study is your choice. Your pregnancy care will not change if you choose to take part in the study or not. You can stop at any time, you do not have to give a reason. **You can ask to have all your data, blood, urine, and saliva (spit) samples destroyed** at any time. An exception to this is in the case of an adverse event, or a serious adverse event, such as if one of our participants or staff were injured, where the information needs to be retained for regulatory reporting.



8. What are the risks of being in this study?

For some participants bruising, dizziness &/or fainting might happen because of the blood test. Some participants may feel upset when discussing issues relating to body weight or when having their body measured. Participants may feel upset when asked about their mental health or stressful life events and how these affect them. Participants may experience some discomfort during the body measurements due to light pinching. These risks are minimised by using qualified & experienced staff.

9. What are the benefits of being in this study?

Our research will provide a better understanding of why babies are born early or with a low birth weight. We hope that we can find out if things like stress, smoking and nutrition when mums are pregnant affects them and their child's chances of getting sick with things like kidney disease later in life. ***There is unlikely to be any benefit to individual participants over the benefits of routine antenatal care.*** Findings from the study may be used by the Bumbira Arts and Culture Program to develop programs aimed at improving the health of mums and bubs.

10. How will my identity be protected?

Any information you provide for this study will remain private & will be stored in a locked filing cabinet or password protected data file. Only the research team will have access to your information. All participants will have a study code so that you are not easily identifiable. Personal details that identify you, such as your name & address, will be removed when the study is complete. Personal information will be accessed, used and stored in accordance with the *Commonwealth Privacy Laws & the NSW Health Records & Information Privacy Act 2002 No 71*. According to the *Children and Young Persons (Care and Protection) Act 1998 (NSW) No 157*, the research team is required to report any information that tells them that children/young persons are at risk of harm.

11. How will I get informed about the results from the study

Posters showing the findings of the study will be available at the Tamworth Aboriginal Medical Service and Land Council. We will also present at community events and run programs with the Bumbira Arts and Culture Program where you can learn about the findings from the study.

For all information about the study and our findings visit our website!

www.gomeroibabies.org.au

Once approved by community, the results will also be presented in scientific journals and at conferences. Individual participants will not be identified in these presentations or publications.

12. Questions about this research

If you have any questions, you can contact the Gomeri Gaaynggal Study Team by:

Email: ggstudy@newcastle.edu.au

Phone: (02) 4042 0372

13. Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee, Reference No. 2021/ETH00488 and the Aboriginal Health and Medical Research Council Ethics Committee, Reference No. 1821/21.

Should you have concerns about your rights as a participant in this research, or you have a complaint about the way the research is conducted, it may be given to the researcher, or, if an independent person is preferred, please contact:

The Hunter New England Research Office:

Address: Level 3, POD, HMRI, Lot 1 Kookaburra Circuit, New Lambton Heights NSW 2305.

Phone: 02 4921 4140.

Email: HNELHD-ResearchOffice@health.nsw.gov.au

Quote the reference number: 2021/ETH00488

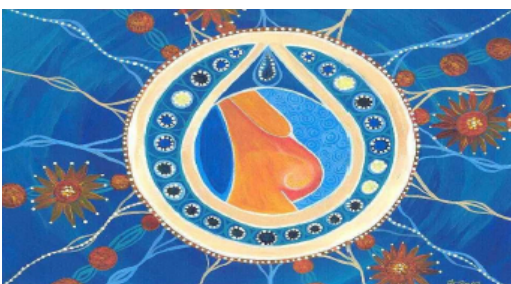
Aboriginal Health & Medical Research Council Ethics Committee:

Address: 35 Harvey Street, Little Bay, NSW 2012

Email: ethics@ahmrc.org.au

and quote the reference number: 1821/21

14. The artist behind our logo



The Gomeri Gaaynggal Study logo titled 'Sacred Mother' was created by Aboriginal Artist Georgina Altona. It expresses the sacredness of woman and the gift of child. Georgina's message for us is that:

"We are all Sacred Mothers."